PC20553-US

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By _____
(Signature of person mailing)

Pamela C. Ancona, Ph.D.
(Typed or printed name of person)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: **Elliot, et al.**	:	Examiner: C. Delacrouix Muirheid
SERIAL NO.: **10/632,281**	:	Unit: **1614**
FILED: **AUGUST 1, 2003**	:	
FOR: **THERAPEUTIC COMBINATIONS OF ERBB KINASE INHIBITORS AND ANTINEOPLASTIC THERAPIES**	:	

Attn: Office of Petitions
Mail Stop Petition
Commissioner of Patents
Alexandria, VA 22313-1450

Sir:

PETITION TO REVIVE AN APPLICATION

UNINTENTIONALLY ABANDONED UNDER 37 C.F.R. § 1.137(B)

The above-identified patent application became abandoned for failure to file a timely and proper reply to a notice or action by the U.S. Patent & Trademark Office. The date of abandonment is the day after the expiration date of the period set for reply in the office action. The mailing date of the outstanding official action in this application was October 7, 2004; therefore, the date of abandonment was January 8, 2005.

Applicants hereby petition for revival of this application. Submitted herewith are the following documents in support of this petition:

(1) Petition fee: The Commissioner is authorized to charge the requisite fee for a large entity under 37 C.F.R. 1.17(m), $1500.00, to deposit account number 16-1445.

(2) The reply to the outstanding official action, i.e., an amendment, is enclosed herewith.

(3) A terminal disclaimer is not required to revive this application because the instant application was filed after June 8, 1995.

(4) Statement: The entire delay in filing the required reply from the due date for the required reply until the filing of a grantable petition under 37 C.F.R. § 1.137(b) was unintentional. The underlying facts regarding the unintentional abandonment of this application are as follows: The instant application was filed by Warner-Lambert Company, in Ann Arbor, MI. Warner-Lambert is a wholly owned subsidiary of Pfizer Inc. Pfizer Inc. has seven U.S. sites at which there are

independent patent departments and each of the seven U.S. sites has a separate and distinct customer number. During the fall of 2003, responsibility for this application was transferred from the Pfizer patent department in Ann Arbor to New York. However, the October 7, 2004 official action was sent to Pfizer's patent department in Ann Arbor rather than New York and the fileroom in Ann Arbor inadvertently failed to notify the fileroom in New York that correspondence had been received in the present application. The undersigned became aware of the outstanding official action in this case and its attendant abandonment due to our failure to reply to the official action when the Examiner handling this application telephoned the undersigned on or about July, 2005, to inquire regarding our response to the outstanding official action. Therefore, the instant application was unintentionally abandoned due to a clerical oversight and appropriate revival is sought.

Respectfully submitted,

Date: August 30, 2005

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Mail Stop Amendment
Commissioner of Patents
Alexandria, VA 22313-1450

Sir:

AMENDMENT

In response to the October 7, 2004 official action, kindly amend the above-identified patent application as follows:

IN THE CLAIMS:

Please cancel claims 3, 5, and 11, without prejudice. Please amend claims 1-2, 6-10, and 12-15 in accordance with 37 C.F.R. § 1.121.

1. (Amended) A method of treating [cell proliferative diseases] cancer comprising administration in a therapeutic regimen of [an] a panerb B inhibitor [of at least one erb B tyrosine kinase] and at least one antineoplastic agent selected from the group consisting of gemcitabine, paclitaxel, docetaxel, cisplatin, carboplatin, etoposide, adriamycin, topotecan, CPT-11, capecitabine, [or] and pharmaceutically acceptable salts thereof[, or ionizing radiation].

2. (Amended) The method of Claim 1 wherein said panerb B inhibitor [of the erbB tyrosine kinase] is an irreversible inhibitor.

3. (Canceled)

4. (Original) The method according to Claim 2 wherein said inhibitor is N-[4-(3-chloro-4-fluoro-phenylamino)-7-(3-morpholin-4-yl-propoxy)-quinazolin-6-yl]-acrylamide.

5. (Canceled)

6. (Amended) The method according to Claim 1 wherein said at least one [said] antineoplastic agent is gemcitabine or a pharmaceutically acceptable salt thereof.

7. (Amended) The method according to Claim [6] 1 wherein said at least one [said] antineoplastic agent is a taxane or a pharmaceutically acceptable salt thereof.

8. (Amended) [A combination] The method according to Claim 1 wherein said at least one antineoplastic agent is selected from the group consisting of paclitaxel [or] and docetaxel.

9. (Amended) A method of treating [a hyperproliferative cellular disorder] cancer comprising administered to a mammal in need of treatment an amount of at least one panerb B [erbB] tyrosine kinase inhibitor and at least one antineoplastic agent according to Claim 1 in an amount sufficient to inhibit [cellular hyperproliferation] cancer cell growth.

10. (Amended) The method of Claim 9 wherein said cancer is selected from the group [comprising] consisting of solid tumors, non-small cell lung cancer, squamous cell carcinoma, glioma, small cell lung carcinoma, endometrial cancer, thyroid cancer,

melanoma, colorectal cancer, bladder cancer, renal cell cancer, pancreatic cancer, head and neck cancer such as esophageal [or] cancer, cervical cancers, ovarian cancer, myeloma, prostate cancer, sarcomas, chronic myelogenous leukemia, and breast cancer.

11. (Canceled)

12. (Amended) The method of Claim [1] 4 comprising administering [CI-1033] said inhibitor in a therapeutic regimen with at least one antineoplastic agent selected from the group [comprising] consisting of gemcitabine, paclitaxel, taxotere, cisplatin, carboplatin, etoposide, adriamycin, topotecan, CPT-11, and capecitabine[, or ionizing radiation].

13. (Amended) The method according to Claim 2, wherein the antineoplastic agent is administered prior to the panerb B [erbB] tyrosine kinase inhibitor.

14. (Amended) The method according to Claim 2, wherein the antineoplastic agent is administered at the same approximate time as the panerb B tyrosine kinase inhibitor .

15. (Amended) The method according to Claim 2, wherein the antineoplastic agent is administered [following] after the panerb B tyrosine kinase inhibitor .

REMARKS

Favorable reconsideration and allowance are respectfully requested. Claims 1-15 are pending. By this amendment, claim 3, 5 and 11 were canceled without prejudice to Applicants' right to pursue one or more divisional applications, and the remaining claims were amended to correct certain clerical errors in the claims and/or to address one or more of the rejections discussed below. Therefore, the amendments to the claims do not introduce new matter. Claims 1-2, 4, 6-10 and 12-15 remain pending and at issue.

Claim Objections & Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 5, 8, and 14-15 were objected to due to various formal matters. In addition, claims 1-4, 6-9, 10, and 11-15 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Each of these objections/rejections are discussed below:

- Various claims, e.g., claim 5, line 2, recited "comprising" in a Markush grouping which should include "consisting of" language. Appropriate correction of such irregularities have been made.
- Claim 8 referred to a "combination" rather than a "method". Accordingly, claim 8 has been amended to refer to a method according to Claim 1.
- Claims 14 and 15 were objected to because the claims should have referred to an "erbB tyrosine kinase inhibitor" rather than a "tyrosine kinase inhibitor". While the claims no longer refer to an "erbB tyrosine kinase inhibitor" for reasons that are discussed below, all references to tyrosine kinase inhibitors now include an appropriate modifier.
- Claim 10 was rejected as indefinite because it referred to "said cancer". Claim 9 has now been amended to refer to a method of treating cancer, so that there is proper antecedent basis in claim 10 for the reference to "said cancer".
- Claims 11-12 were rejected as indefinite because the claims referred to "CI-1033". The claims have been amended to refer to the proper compound name recited in claim 4.
- Claim 12 was rejected as indefinite because the claim referred to "taxotere" without sufficient antecedent basis. The claim has been amended accordingly.
- Claims 1 and 9 were rejected as indefinite because of the limitations "cell proliferative diseases" and "hyperproliferative cellular disorder". The Examiner stated that the specification does not clearly set forth the definition of these limitations and the metes and bounds of the patent protection desired are unclear. Without conceding the propriety of the rejection and purely in the interest of advancing prosecution on the merits, Applicants have amended the claims to refer to methods of treating cancer, rather than methods of treating cell proliferative diseases or methods of treating hyperproliferative cellular disorders.

Rejections Under 35 U.S.C. §§ 102 & 103

Claims 1, 2, 5-8, 9-10, and 13-15 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by WO9931140 ("WO '140"). Further, claims 1-3, 5, and 9-10 were rejected under 35 U.S.C. § 102(a) as anticipated by WO 0241828 ("WO '828"). Finally, claims 1-4, 5, 11, and 12 were rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Rao et al. Int. J. Radiation Oncology Biol. Phys. Vol. 48 (5): 1519-28 (2000) ("Rao").

WO '140 was cited as a disclosure of a method for treating cancers characterized by an overexpression of ErbB2 comprising administering to the patient an effective amount of an anti-ErbB2 antibody in combination with a chemotherapeutic agent. Similarly, WO '828 was cited as a disclosure of a method of treating cancer by administering an erbB2 inhibitor alone or in combination with other anticancer agents. Finally, Rao was cited as a disclosure of a method of treating ErbB-over expressing human breast cancer cells with a combination of ionizing radiation and CI-1033.

Applicants traverse these rejections, addressed collectively below.

As to WO '140 and WO '828, the instant claims are notably different than the disclosures of the cited references because the claims are directed to the administration of a panerb inhibitor rather than an ErbB2-selective inhibitor. Therefore the claims are not anticipated by WO '140 or WO '828 because these references simply do not disclose the claimed invention.

With respect to Rao, the claims have been amended to delete the reference to the use of radiation in the claimed method. This amendment was made in an effort to advance prosecution and it should not be taken as an admission that the Examiner's rejection has merit. On the contrary, Applicants reserve the right to pursue the subject matter excised from the current claims in one or more pending divisional applications.

In view of the foregoing amendments and remarks, favorable reconsideration and withdrawal of the Sections 102 and 103 rejections are respectfully requested.

CONCLUSION

Favorable consideration of the foregoing amendments and remarks are respectfully requested. If, after consideration of these remarks the Examiner maintains that there are issues that remain an impediment to allowance, he is invited to telephone the undersigned to discuss such issues.

Respectfully submitted,

Date: August 30, 2005

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